Missouri Pharmacy Program – Preferred Drug List

Hepatitis C Therapy

Effective 08/01/2005
Revised 10/01/2015

Preferred Agents

- Peg-Intron®
- Pegasys® Vial/Syringe
- Pegasys® Convenience Pack
- Pegasys® Proclick
- Viekira Pak™

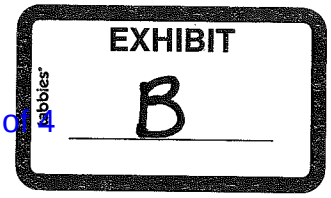
Non-Preferred Agents

- Harvoni®
- Olysio™
- Sovaldi®
- **Victrelis®**
- **Incivek®**

Approval Criteria

For Viekira Pak™

- **Diagnosis of Hepatitis C**
- **Must have Genotype 1**
- **Adult patients age ≥ 18 years old**
- **Fibrosis score equal to or greater than F3**
- **Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months**
- **Baseline viral load must be submitted**
- **Must be prescribed with ribavirin for Genotype 1a with or without cirrhosis and for Genotype 1b with cirrhosis**
- **Maximum length of therapy approval of 12 weeks for Genotype 1a without cirrhosis and Genotype 1b with or without cirrhosis – subject to Clinical Consultant approval**
- **Maximum length of therapy approval of 24 weeks for Genotype 1a with cirrhosis dependent on prior treatment history – subject to Clinical Consultant approval**
- **Viral load results submitted at week 12 and week 24 (week 12 results must be less than 25 IU/mL if duration of treatment is 24 weeks)**
- **Prescription claim for Viekira Pak™ with billed units = 112 tablets for 28 day supply.**



- **No more than a 7 day gap between prior claim and incoming claim with a 168 day look back**

For Harvoni®

- **Diagnosis of Hepatitis C**
- **Must have Genotype 1**
- **Trial and failure of Viekira Pak™**
- **Adult patients age ≥ 18 years old**
- **Fibrosis score equal to or greater than F3**
- **Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months**
- **Baseline viral load must be submitted**
- **Maximum length of therapy approval of 12 weeks for treatment-naïve with or without cirrhosis and treatment-experienced without cirrhosis – subject to Clinical Consultant approval.**
- **Maximum length of therapy approval of 24 weeks for treatment-experienced with cirrhosis – subject to Clinical Consultant approval**
- **Viral load results submitted at week 12 and week 24 (week 12 results must be less than 25 IU/mL if duration of treatment is 24 weeks)**
- **Prescription claim for Harvoni® with billed units = 28 tablets for 28 day supply.**
- **No more than a 7 day gap between prior claim and incoming claim with a 168 day look back**

For Sovaldi®

- Diagnosis of Hepatitis C
- Adult patients age ≥ 18 years old
- Must have Genotype 1 or 2 or 3 or 4
- **If Genotype 1 a trial and failure of Viekira Pak™**
- Fibrosis score equal to or greater than F3 for Genotype 1, 2, or 4
- Fibrosis score equal to or greater than F2 for Genotype 3
- Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months
- Baseline viral load must be submitted
- Must be prescribed with ribavirin or ribavirin + PEG
- Maximum length of therapy approval of 24 weeks – subject to Clinical Consultant approval
- For Sovaldi and Olysio combination therapy consideration
  - Must be defined interferon ineligible (see Appendix A)
  - Must be Genotype 1
  - **Trial and failure of Viekira Pak™**
  - Must be prescribed with Ribavirin
  - Max approval 12 weeks
- Ongoing therapy – Must be submitted at week 12 and week 24:

- Negative Urine Alcohol and Illicit Drug Screen results submitted done within 7 days prior to refill request
- Viral load results submitted and less than 25 IU/mL

- **Prescription claim for Sovaldi® (sofosbuvir) with billed units = 28 tablets for 28 day supply.**
- **No more than a 7 day gap between prior claim and incoming claim with a 168 day look back.**

For Olysio™

- Diagnosis of Hepatitis C
- Adult patients age ≥ 18 years old
- Must be Genotype 1 or 4
  - If Genotype 1 must have Subtype
    - If Subtype 1A must be negative for polymorphism Q80K
    - **Trial and failure of Viekira Pak™**
- Fibrosis score equal to or greater than F3
- Negative Urine Alcohol and Illicit Drug Screen results submitted for most current 3 months
- Baseline viral load must be submitted
- Must be prescribed with ribavirin + PEG
- Maximum length of therapy approval of 24 weeks – subject to Clinical Consultant approval
- For Olysio and Sovaldi combination therapy consideration
  - **Trial and failure of Viekira Pak™**
  - Must be defined interferon ineligible (see Appendix A)
  - Must be Genotype 1
  - Must be prescribed with Ribavirin
  - Max approval 12 weeks
- Must not have been treated with an oral protease inhibitor indicated for HCV in the past
- Ongoing therapy – Must be submitted at week 12 and week 24:
  - Negative Urine Alcohol and Illicit Drug Screen results submitted done within 7 days prior to refill request
  - Viral load results submitted and less than 25 IU/mL
- **Prescription claim for Olysio™ (simeprevir) with billed units = 28 tablets for 28 day supply.**
- **No more than a 7 day gap between prior claim and incoming claim with a 168 day look back**

Denial Criteria

- Lack of appropriate diagnosis
- Less than 18 years of age
- Pregnancy
- Genotype 5 or 6
- Sovaldi or Olysio as monotherapy
- For Olysio therapy for Genotype 1a with Q80K polymorphism
- Viral load greater than 25 IU/mL at treatment week 4 or beyond
- Evidence of alcohol or illicit drugs use anytime during treatment
- Positive alcohol and illicit drug urine screen (without current prescription)
- Combination of Sovaldi and Olysio for genotypes 2, 3, 4, 5 or 6
- Metavir fibrosis score of less than F3 for genotypes 1, 2 or 4
- Metavir fibrosis score of less than F2 for genotype 3
- For Olysio therapy - previous treatment with an oral protease inhibitor indicated for HCV
- Lack of approval criteria
- **For Viekira Pak™:**
  - **Billed units on the claim <112 tablets for 28 days and**
  - **Billed units on the claim >112 tablets for 28 days.**
  - **Gap in therapy >7 days from previous claim**
- **For Sovaldi®, Olysio™ and Harvoni®:**
  - **Billed units on the claim <28 tablets for 28 days and**
  - **Billed units on the claim >28 tablets for 28 days.**
  - **Gap in therapy >7 days from previous claim**
- **For Sovaldi®, Olysio™ and Harvoni®:**
  - **Lack of trial and failure of Viekira Pak™ if treating genotype 1**